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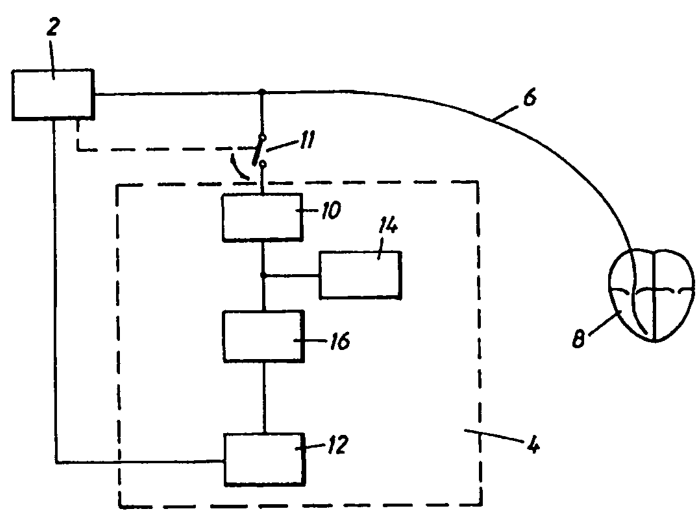

(57) Abstract

A heart stimulator comprises a pulse generator (2) devised for producing stimulation pulses of varying amplitudes. A lead (6) is intended to be introduced into the heart (8) of a patient and connected to the pulse generator for delivering stimulation pulses to the heart. In order to determine a stimulation threshold value said pulse generator is controlled to deliver stimulation pulses of different amplitudes, each stimulation pulse being followed by a test pulse of a predetermined high constant amplitude delivered in the refractory period of the heart (8). Measurement means (10) are provided to measure the electrode signal picked up by the lead after the test pulse, and comparator means (12) are provided for comparing the electrode signals with each other, a change in the measured signal between two stimulation pulses of different amplitudes indicating the threshold value to be situated between the two stimulation amplitudes.

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HEART STIMULATOR DETERMINING STIMULATION THRESHOLD

Technical Field

The present invention relates to a heart stimulator comprising a pulse generator devised for producing stimulation pulses of varying amplitudes, a lead being intended to be introduced into the heart of a patient and connected to the pulse generator for delivering stimulation pulses to the heart.

Background Art

To reduce the energy consumption of heart stimulators an automatic threshold search function, a so called AUTOCAPTURE™ function, is used to maintain the energy of the stimulation pulses at a level just above that which is needed to effectuate capture, cf. e.g. US-A-5,458,623. A reliable detection of the evoked response, which then is necessary, is, however, not a simple matter, especially when it is desired to sense the evoked response with the same electrode as the one delivering the stimulation pulse. The reason therefor resides in the fact that the evoked response potential is small in amplitude compared to the residual polarization charge. The residual charge decays exponentially but tends to dominate the evoked potential for several hundreds of milliseconds after the stimulation. If the polarization is too high, it could be wrongly interpreted by the evoked response detector as a capture, i.e. contraction of the heart. The AUTOCAPTURE™ algorithm could then by mistake adjust the output amplitude of the stimulation pulse to a value below the actual capture level, which will result in no capture. If the used pacing lead has significant polarization this could consequently disturb the AUTOCAPTURE™ function and result in loss of capture.

Several attempts have been made to solve the lead polarization problems in connection with evoked response detection. One possibility is to use low polarization leads. This is, however, not always possible.

Another method is described in US-A-5,417,718, which discloses a system for maintaining capture wherein electrical post-stimulus signal of the heart, following delivery of a stimulation pulse, is compared to a polarization template, determined during a capture verification test. A prescribed difference between the polarization template and the post-stimulus signal indicates capture. Otherwise loss of capture is presumed and the stimulation energy is increased a predetermined amount to obtain capture.

In US-A-5,697,957 a method and an apparatus for extracting an evoked response component from a sensed cardiac signal by suppressing electrode polarization are descsribed. An autocorrelation function is then calculated according to an autocorrelation algorithm, and is applied to the sensed cardiac signal. The autocorrelated signal thus obtained and the sensed cardiac signal are then normalized to each other and a difference between these two normalized signals is formed, thereby extracting the evoked response component if present in the said cardiac signal.

There is mostly at least one significant slope in the bipolar measured IEGM signal, which makes it possible to discriminate the evoked response signal from slowly varying signals such as polarization signals. Thus in US-A-5,431,693 a method of verifying capture of the heart by a cardiac pacemaker is described. Observing that the non-capture potential is exponential in form and the evoked capture potential, while generally exponential in form, has one or more small-amplitude perturbations superimposed on the exponential wave form, these perturbations are enhanced for ease of detection by processing the wave form signal by differentiation to form the second derivative of the evoked response signal for analysis for the evoked reponse detection.

Unipolar detection of evoked response signals is however not possible by this technique. Abrupt slope changes or superimposed small-amplitude perturbations are levelled out

if the measurements are made over a longer distance from the electrode to the stimulator casing.

This is illustrated in figure 1, which shows the unfiltered measured electrode signal picked up by a unipolar electrode configuration, the upper curve in the figure, and a bipolar electrode configuration, the lower curve in the figure.

In the co-pending Swedish patent application No. (98 E 2013) a new technique is described for solving the polarization problem in connection with evoked response detection. This technique is not based on any slope measurements on the sensed electrode signal, but on determination of the polarization signal for different stimulation amplitudes for then subtracting the polarization signal from the sensed electrode signal to obtain the true evoked response signal. This determination of the polarization is based on the observations that the evoked response signal amplitude is fairly constant, independent of the stimulation pulse amplitude, whereas the electrode polarization is approximately linearly dependent on the stimulation pulse amplitude for a constant pulse duration, cf. Swedish patent application No. 9703600-8.

The above mentioned manner of determining the polarization presumes that the stimulation threshold value is known.

The purpose of the present invention is therefore to propose a technique for determining the stimulation threshold value which is suitable to use in connection with the new way of determining the polarization as described in said co-pending patent application.

Disclosure of the Invention

This purpose is obtained with a heart stimulator according to the introductory portion of the description having the characterizing features of claim 1.

Thus with the heart stimulator according to the invention the average amplitudes of the signals following each test pulse are determined, and as long as there is capture on the stimulation pulse, the amplitude of the polarization following the test pulse will show small variations. When the stimulation pulse no longer causes capture, there will be a capture on the test pulse and the amplitude of the following signals will change significantly, thus indicating that the amplitude of stimulation pulse has passed the threshold value. Thus, in this way the threshold value is localized.

The stimulation threshold can be determined before or during the polarization algorithm is running in the evoked response detector according to the co-pending patent application No. .... (our ref.: 98P2014SE), which is an important advantage.

According to advantageous embodiments of the heart stimulator according to the invention calculation means are provided to calculate the average value of the amplitude of the electrode signal picked up after each test pulse, said comparator means comparing said average values with each other to detect significant changes in said average values for use in the determination of threshold value. The measurement means are preferably adapted to sample and digitize the measured electrode signal during a predetermined time interval after the delivery of the test pulse and said calculation means are adapted to calculate an average value of said samples. In this way small variations and other interferences in the measured electrode signals are suppressed.

Brief Description of the Drawings

To explain the invention more in detail an embodiment of the heart stimulator according to the invention will now be described with reference to the drawings, on which

figure 1 shows the unfiltered electrode signal measured with a unipolar electrode configuration, the upper curve, and with a bipolar electrode configuration, the lower curve,

figure 2 is a block diagram of the principal layout of the heart stimulator according to the invention, and

figure 3 is a block diagram of an embodiment of the evoked response detector used in the heart stimulator according to the invention.

Description of Preferred Embodiments

Fig. 2 shows a block diagram of the principal layout of the heart stimulator according to the invention. The stimulator comprises a pulse generator 2 which through a lead 6 is connected to the heart 8 of a patient. The pulse generator 2 is devised to produce stimulation pulses of varying amplitudes which through the lead 6 are transferred to the heart 8. An evoked response detector 4 is also connected to the lead 6. The evoked response detector 4 comprises a filter and measurement means 10 for measuring the electrode signal picked up by the lead 6.

The measured electrode signal is supplied to calculating means 16 and to comparator means 12 for comparing the measured electrode signals with each other.

The filter and measurement means 10 is disconnected by the switch 11 from the lead 6 during stimulation.

Timing means 14 are provided for determining a time interval after the delivery of the test pulse during which the electrode signal is measured and stored. The measurement means 10 is adapted to sample and digitize the measured electrode signal during this time interval and the calculation means 16 are adapted to calculate an average value of these samples. This average value is then supplied to the comparator means 12 for use in the subsequent comparison step.

As test pulse the ordinary backup pulse of the heart stimulator can preferably be used.

Fig. 3 shows in more detail an embodiment of the evoked response detector used in the heart stimulator according to the invention. The heart electrode signal picked up by the lead 6 in fig. 2 is then supplied to a highpass filter 20. An amplifier 22 and an A/D converter 24 are provided for amplifying and A/D converting respectively the filtered signal. The block 26 comprises a digital signal processor for measuring, calculating and comparing the signals picked up by the lead 6.

Thus in the embodiment shown in fig. 3 the algorithm for determining the stimulation threshold value is implemented in software by use of a microprocessor. Instead of a microprocessor this algorithm can also be implemented in random logic, which means realization by ordinary logic element, that is logic gates.

The detector can also be implemented in the electronics of the heart stimulator according to the invention by use of switch capacitor (SC) technique. The algorithm is then implemented in SC technique, where different capacitors serve as memory elements for storing the different electrode potentials and SC-adding, subtracting and multiplying circuits are used for performing the necessary calculations.

The function of the embodiment illustrated in figures 2 and 3 is as follows.

Stimulation pulses are delivered in a Vario cycle, i.e. the procedure is started with a stimulation pulse with a high amplitude and then stimulation pulses of successively lower amplitudes are delivered. After each stimulation pulse a test pulse of a high constant amplitude is sent out. This test pulse can preferably be the backup pulse of the heart stimulator in question. The average amplitude of the measured signal after the test pulse is calculated as described above. As long as the delivered stimulation pulses result in

capture, the measured electrode signal after the test pulse will be a pure polarization signal, and the average amplitude of these polarization signals will exhibit only small variations as the test pulses have a constant amplitude.

When the amplitude of the stimulation pulse is lowered such that capture is no longer obtained, the test pulse will give rise to capture and the average amplitude of the electrode signal measured after the test pulse will change significantly and become much more negative than the previous signal amplitudes. Thus, this change in the measured signal amplitude indicates that the threshold is passed and the threshold value determined.

If the lowest possible stimulation amplitude is reached, e.g. 0.3 V, and no loss of capture is detected, the average electrode signal following the 0.3 V stimulation pulse is measured and compared with a predetermined value. There are three possible situations explaining the fact that no loss of capture is found, namely

1. The stimulation threshold is below 0.3 V and the absolute average value of the measured signal is larger than the mentioned predetermined value.

2. The stimulation threshold is below 0.3 V and the absolute average value of the measured electrode signal is smaller than the mentioned predetermined value.

3. The stimulation threshold is above 0.3 V, which consequently results in the loss of capture when stimulating with a 0.3 V stimulation pulse, but the absolute average value of the measured electrode signal is smaller than the mentioned predetermined value and therefor cannot be detected after the test pulse.

If the threshold is found and is above 0.3 V or if the situation according to point 1 prevails, the polarization signal Pol_{step} for the voltage step of the changing stimulation pulse amplitude can be calculated, either from

the cycle of successively changing stimulation pulses already carried through, if the measured electrode signals following the stimulation pulse have been stored, or by starting a new such cycle running down to the threshold amplitude plus one voltage step.

If the threshold is not found and the situation according to point 1 above is not fulfilled, the explanations according to points 2 or 3 must be correct. In that case the measured electrode signal is too low to make a reliable detection of evoked response possible and if the heart stimulator in question is provided with an AUTOCAPTURE™ function it must not be activated.

As an alternative to the above described procedure of successively lowering the stimulation amplitude from a high starting amplitude (Vario cycle), the procedure for determining the threshold can be as follows.

The cycle is started by stimulating a predetermined number of times with a high stimulation amplitude, e.g. 4.5 V, followed by a test pulse equal to a backup pulse of 4.5 V. Then the stimulation amplitude is changed to the lowest possible stimulation amplitude, e.g. 0.3 V, if 0.3 V is the voltage step for the heart stimulator in question, followed by backup pulses of 4.5 V. The average amplitude of the measured polarization signals following the backup pulses are then compared and it is decided whether there was a capture or not after the 0.3 V stimulation pulses according to the above stated criteria. If there was capture, stimulation is performed with stimulation pulses of 4.5 V and then 0.6 V (0.3 V + 0.3 V). From the measured electrode signals after the stimulation pulses, which resulted in captures, the Pol_{step} signal is calculated.

If there was not a capture for a stimulation amplitude of 0.3 V, the lower stimulation amplitude is increased with the voltage step of 0.3 and the procedure is repeated until the threshold value is reached.

If the stimulation threshold value is above a predetermined value, for both the above described threshold searching methods, the Pol_{step} signal can be directly calculatead from the polarization signals measured for stimulation amplitudes below the threshold value.

CLAIMS

1. A heart stimulator comprising a pulse generator (2) devised for producing stimulation pulses of varying amplitudes, a lead (6) being intended to be introduced into the heart (8) of a patient and connected to the pulse generator for delivering stimulation pulses to the heart, characterized in that, in order to determine a stimulation threshold value, said pulse generator (2) being controlled to deliver stimulation pulses of different amplitudes, each stimulation pulse being followed by a test pulse of a predetermined high constant amplitude delivered in the refractory period of the heart (8) in that measurement means (10) are provided to measure the electrode signal picked up by the lead after the test pulse, and in that comparator means are provided for comparing said electrode signals with each other, a change in said measured signal between two stimulation pulses of different amplitudes indicating the threshold value to be situated between these two stimulation amplitudes.

2. The heart stimulator according to claim 1, characterized in that said pulse generator is controlled to deliver stimulation pulses of successively lower amplitudes, starting with a high pulse amplitude, well above the threshold value, a significant change in the measured electrode signal between two consecutive stimulation pulses being indicated as a passage below the threshold value of the stimulation pulse amplitude.

3. The heart stimulator according to claim 1, characterized in that said pulse generator is controlled to produce stimulation pulses of two different amplitudes, said amplitudes being selected equal to the highest available stimulation amplitude and the lowest

stimulation amplitude respectively, and, if the threshold value is found to be situated between these two stimulation amplitudes, said pulse generator is controlled to increase said lowest stimulation amplitude by a predetermined step and the signal after the associated backup pulse is measured and, if the threshold value is found to be situated between these two latter stimulation amplitudes, the pulse generator is controlled to further increase the stimulation amplitude by said predetermined step and the procedure is repeated until the stimulation amplitude is found to have passed the threshold value.

4. The heart stimulator according to any of the preceding claims, characterized in that calculation means are provided to calculate the average value of the amplitude of the electrode signal picked up after each test pulse, said comparator means comparing said average values with each other to detect significant changes in said average values for use in the determination of the threshold value.

5. The heart stimulator according to any of the preceding claims, characterized in that said test pulse is an ordinary backup pulse.

6. The heart stimulator according to claims 4 or 5, characterized in that said measurement means are adapted to sample and digitize the measured electrode signal during a predetermined time interval after the delivery of the test pulse, and in that said calculation means are adapted to calculate an average value of said samples.

Fig. 1

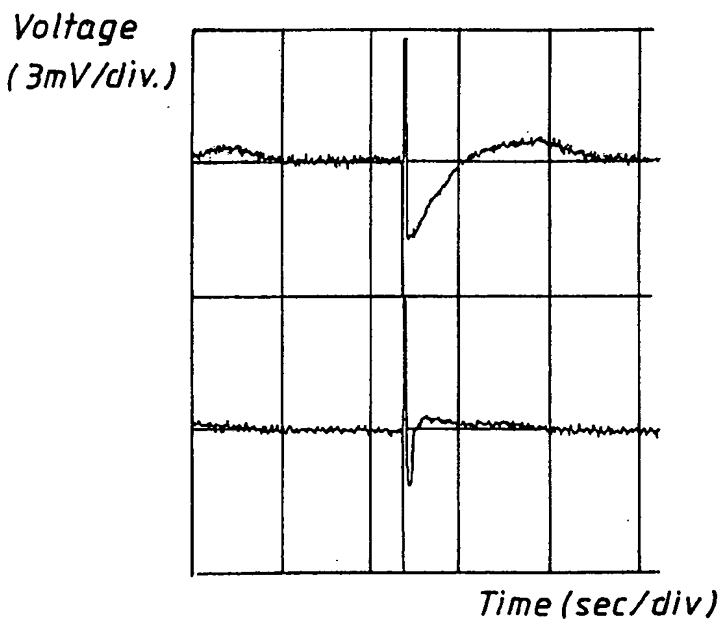


Fig. 2

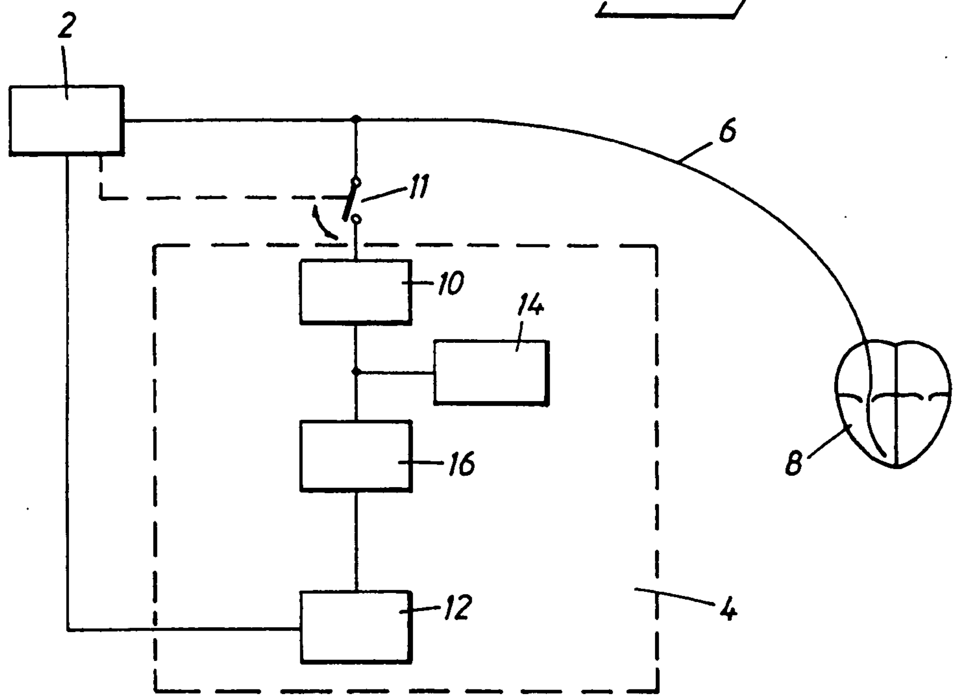
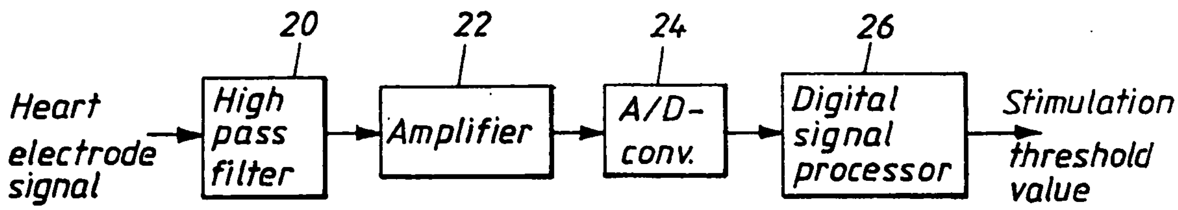

2
6
11
10
14
16
8
12
4

Fig. 3


20
22
24
26
Heart electrode signal
High pass filter
Amplifier
A/D-conv.
Digital signal processor
Stimulation threshold value

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01018

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5741312 A (BERNARDUS F.M. VONK ET AL.), 21 April 1998 (21.04.98), column 1, line 66 - column 2, line 30, figure 4, abstract	1
Y		2-5
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Y	US 4766902 A (EDWARD A. SCHROEPPEL), 30 August 1988 (30.08.88), column 2, line 18 - line 57, figure 3, abstract	2-5
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A	US 5391192 A (RICHARD M.T. LU ET AL.), 21 February 1995 (21.02.95), figure 1, abstract	1-6
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5458623 A (RICHARD M.T. LU ET AL.), 17 October 1995 (17.10.95), figure 2, abstract	1-6

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INTERNATIONAL SEARCH REPORT
Information on patent family members

28/09/99

International application No.
PCT/SE 99/01018

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5741312 A	21/04/98	EP 0870516 A	14/10/98
US 4766902 A	30/08/88	NONE	
US 5391192 A	21/02/95	NONE	
US 5458623 A	17/10/95	NONE	